

## REMARKS

Claims 1-19 and 24-65 are pending. Claims 20-23 have been cancelled. Claims 3-10, 64 and 65 are withdrawn.

According to the Official Action claims 1, 2 and 12-63 are rejected under 35 USC 112, first paragraph on the basis that the specification does not reasonably provide enablement for making solvates and polymorphs. This is respectfully traversed.

The examiner's attention is drawn to paragraphs [000228] and [000230] of the specification. Paragraph [000228] describes procedures and steps to prepare polymorphs of the compounds of formula (I). Paragraph [000230] describes procedures and steps for preparing solvates.

When considering the enablement requirement, the person who must be able to utilize the specification to make or use the invention is one "skilled in the art to which the invention pertains or with which it is most nearly connected" and so a reasonable degree of expertise can be assumed. One skilled in the art would be able to make polymorphs and solvates of the compounds of formula (I) based on the specification and their knowledge of the art.

Therefore, it is respectfully requested that this rejection be withdrawn.

According to the Official Action, claims 24-63 are rejected under 35 USC 112, first paragraph as not being enabling for conditions other than treating type II diabetes, insulin resistance and hypercholesteremia.

This rejection is respectfully traversed.

It is submitted that the application is enabling for the conditions and diseases included in claims 24-63. The fact that some experimentation is required does not condemn the specification nor does the fact that the skilled worker may need to consult outside references. For example in *Ex parte Jackson* 217 USPQ 804, the Board of Appeals referring to *Ansul v. Uniroyal* 169 USPQ 759 (2d Cir 1971) and *In re Rainer* 146 USPQ 218 (CCPA 1965) pointed out that

determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness having regard to the nature of the invention. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable determination of how to practice a desired embodiment of the invention claimed.

As stated above, when considering the enablement test, the person who must be able to utilize the specification to make or use the invention is one "skilled in the art to which the invention pertains or with which it is most nearly connected" and so a reasonable degree of expertise can be assumed. In *In re Howarth* (210 USPQ 689 (CCPA 1981) the Court of Customs and Patent Appeals noted that the relevant art was not only the actual knowledge that the worker had but also what he or she would know to search out. The court pointed out

Well known text books in English are obvious research materials. Similarly, public records concerning U. S. patents are likely to be checked and information in them is reasonably accessible in view of published abstracts and our classification system. ... We do not exclude the possibility that foreign patents and foreign language printed publications may also be relevant...

On the other hand, when no guide at all has been given, as here, an applicant must show that anyone skilled in the art would actually have possessed the requisite knowledge or would reasonably be expected to check the source which the

applicant relies upon to complete his disclosure and would be able to locate the information with no more than reasonable diligence.

In this case, one skilled in the art would look to procedures and protocols in the pharmaceutical arts.

In the chemical field, there have been cases that have held that as long as the means for carrying out the invention is fully disclosed, there is no absolute requirement to include working examples in the specification and that the absence of such examples does not ipso facto mean that the patent is invalid for failure to provide enabling disclosure or describe the best mode. *In re Stephens* 529 F2d 1343, 188 USPQ 659 (CCPA 1976) *In re Strahilevitz* 668 F2d 1229, 212 USPQ 561 (CCPA 1982).

In addition to the references submitted with the previous response, applicants wish to draw the Examiner's attention to paragraphs [0006] to [0013] of the specification. Based on these materials and the data included in the specification, it is submitted that the claims 24-63 are enabled.

Accordingly, it is respectfully requested that this rejection be withdrawn.

Terminal disclaimers in respect of US patents 6,444,816 and 6,369,067 are attached.

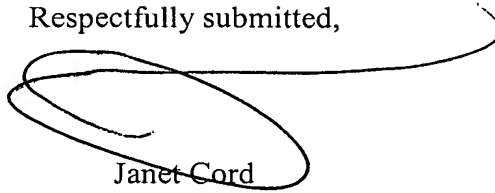
According to the Official Action, claims 1, 2, 11-17 and 20-63 are rejected as being anticipated by Das ('816). The rejection of claims 1, 2, 11-17 and 20-63 under 35 USC 102(e) as being anticipated by Das ('816) is traversed. However, in view of the filing of the terminal disclaimer in respect of US patent 6,444,816 it is respectfully requested that this rejection be withdrawn.

According to the Official Action, claims 1, 2, 11-17 and 20-63 are rejected as being anticipated by Gurram ('067). The rejection of claims 1, 2, 11-17 and 20-63 under 35 USC 102(e) as being anticipated by Gurram ('067) is traversed.

However, in view of the filing of the terminal disclaimer in respect of US patent 6,444,816 it is respectfully requested that this rejection be withdrawn.

Accordingly, it is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Janet Cord", is written over the printed name. The signature is fluid and cursive, with a large loop at the end.

Janet Cord

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